

CLAIMS

1. A method for diagnosing prostate cancer, the method comprising the step of detecting the presence or absence of an expression product of a HML-2 endogenous retrovirus in a patient sample.

5 2. The method of claim 1, wherein the expression product is a RNA or a polypeptide.

3. The method of any preceding claim, wherein the patient sample is a prostate sample or a blood sample.

4. The method of any preceding claim, wherein the expression product is a RNA having the following formula: N<sub>1</sub>—N<sub>2</sub>—N<sub>3</sub>—N<sub>4</sub>—N<sub>5</sub>—polyA, wherein: N<sub>1</sub> has at least x% sequence identity to SEQ ID 155; N<sub>2</sub> has at least x% sequence identity to SEQ ID 156; N<sub>3</sub> has at least x% sequence identity to SEQ ID 6; N<sub>4</sub> comprises any RNA sequence; N<sub>5</sub> has at least x% sequence identity to SEQ ID 5; and at least one of N<sub>1</sub> or N<sub>5</sub> is present, but N<sub>2</sub>, N<sub>3</sub>, N<sub>4</sub> and polyA are optional.

5 5. The method of claim 4, wherein the RNA comprises N<sub>1</sub>.

6. The method of claim 5, wherein N<sub>1</sub> is at the 5' end of the RNA.

7. The method of claim 4, wherein N<sub>4</sub> comprises a polypeptide-coding sequence.

8. The method of claim 2, wherein the polypeptide is encoded by a mRNA having the following formula: N<sub>1</sub>—N<sub>2</sub>—N<sub>3</sub>—N<sub>4</sub>—N<sub>5</sub>—polyA, as defined in claim 4.

9. The method of claim 8, wherein the mRNA encodes one or more of the following HML-2 polypeptides: gag, prt, pol, env, cORF, tat.

20 10. The method of claim 8 or claim 9, wherein the polypeptide is detected using an antibody.

25 11. A method for diagnosing prostate cancer, the method comprising the steps of: (a) obtaining a patient sample containing prostate cells; and (b) detecting the presence or absence of an expression product of a HML-2 endogenous retrovirus in the patient sample.

12. The method of claim 11, wherein step (b) utilizes the method of any one of claims 1 to 10.

13. The method of claim 11 or claim 12, wherein step (b) is preceded by a step of enriching RNA in the patient sample.

14. The method of any one of claims 1 to 6 or 11 to 13, wherein the expression product is detected using PCR, SDA, SSSR, LCR, TMA or NASBA.

5 15. The method of claim 14, wherein the PCT is RT-PCR.

16. Isolated polynucleotide for use in the diagnosis of prostate cancer, the isolated polynucleotide comprising: (a) the nucleotide sequence  $N_1-N_2-N_3-N_4-N_5$ —polyA as defined in claim 4; (b) a fragment of at least 7 nucleotides of nucleotide sequence  $N_1-N_2-N_3-N_4-N_5$  as defined above; (c) a nucleotide sequence having at least 50% identity to nucleotide sequence  $N_1-N_2-N_3-N_4-N_5$  as defined above; or (d) the complement of (a), (b) or (c).

17. Isolated polynucleotide of claim 16, wherein fragment (b) is from  $N_1$ .

18. Isolated polynucleotide of claim 16, comprising one of SEQ IDs 7-39, SEQ IDs 44-45, SEQ IDs 59-91, SEQ ID 93, SEQ ID 95, SEQ ID 97, SEQ IDs 99-105, SEQ ID 107, SEQ IDs 110-145, SEQ IDs 150-157, or SEQ IDs 161-225.

19. Isolated polynucleotide comprising one of SEQ IDs 59-82.

20. Isolated polynucleotide of claim 19 for use in the diagnosis or treatment of testicular cancer, multiple sclerosis or insulin-dependent diabetes mellitus.

21. Isolated polynucleotide having formula 5'-A-B-C-3', wherein: -A- is a nucleotide sequence consisting of  $a$  nucleotides; -C- is a nucleotide sequence consisting of  $c$  nucleotides; -B- is a nucleotide sequence consisting of either (a) a fragment of 7 or more nucleotides of nucleotide sequence  $N_1-N_2-N_3-N_4-N_5$  as defined in claim 4 or (b) the complement of a fragment of 7 or more nucleotides of nucleotide sequence  $N_1-N_2-N_3-N_4-N_5$  as defined in claim 4; and said polynucleotide is neither (a) a fragment of nucleotide sequence  $N_1-N_2-N_3-N_4-N_5$  or (b) the complement of a fragment of nucleotide sequence  $N_1-N_2-N_3-N_4-N_5$ ; and wherein  $a+c \geq 1$ .

22. Isolated polynucleotide of claim 21, wherein B comprises a fragment of 7 or more nucleotides from one or more of SEQ ID NOS: 7-39, 44-45, 59-91, 93, 95, 97, 99-105, 107, 110-145, 150-157, and 161-225.

23. Isolated polynucleotide of any one of claims 15 to 22, comprising a detectable label.

5 24. A kit comprising primers for amplifying a template sequence contained within a RNA according to claim 16, the kit comprising a first primer and a second primer, wherein the first primer is substantially complementary to said template sequence and the second primer is substantially complementary to a complement of said template sequence, wherein the parts of said primers which have substantial complementarity define the termini of the template RNA sequence to be amplified.

25. An isolated polypeptide for use in the diagnosis of prostate cancer, the polypeptide comprising: (a) an amino acid sequence selected from the group consisting of SEQ IDs 109, 146, 147, 148 and 149; (b) a fragment of at least 7 amino acids of (a); or (c) a polypeptide sequence having at least 50% identity to (a).

26. An isolated polypeptide having formula  $\text{NH}_2\text{-A-B-C-COOH}$ , wherein: A is a polypeptide sequence consisting of  $a$  amino acids; C is a polypeptide sequence consisting of  $c$  amino acids; B is a polypeptide sequence consisting of a fragment of at least 5 amino acids of an amino acid sequence selected from the group consisting of SEQ IDs 146, 147, 148, 149, 115, 109, 110 and 111; and said polypeptide is not a fragment of polypeptide sequence SEQ ID 146, 147, 148, 149, 115, 109, 110 or 111; and wherein  $a+c \geq 1$ .

27. Polypeptide of claim 25 or 26, attached to a solid support.

28. Polypeptide of claim 25 or 26, comprising a detectable label.

29. Antibody for use in the diagnosis of prostate cancer, the antibody being able to specifically bind to the polypeptide of claim 25 or claim 26.

25 30. Antibody of claim 29, wherein the antibody is a monoclonal antibody.

31. Antibody of claim 29 or claim 30, attached to a solid support.

32. A pharmaceutical composition comprising polynucleotide as defined in any one of claims 15 to 22, polypeptide as defined in any one of claims 25 to 26, or antibody as defined in any one of claims to claim 29 to 30; and a pharmaceutically acceptable carrier.

33. The composition of claim 32, for use as a medicament.

5 34. The use of polynucleotide as defined in any one of claims 15 to 22, polypeptide as defined in any one of claims 25 to 26, or antibody as defined in any one of claims to claim 29 to 30, in the manufacture of a medicament for treating prostate cancer.

35. A method of screening for compounds with activity against prostate cancer, comprising: contacting a test compound with a tissue sample derived from a cell in which HML-2 expression is up regulated; monitoring HML 2 expression in the sample; and determining the anti-cancer efficacy of the test compound.

36. The use of an inhibitor of a HML-2 protease in the manufacture of a medicament for treating prostate cancer.

37. The use of a transdominant negative mutant of HML-2 cORF in the manufacture of a medicament for treating prostate cancer.

38. A composition comprising (a) a prostate cell and (b) polynucleotide as defined in any one of claims 15 to 23, a kit as defined in claim 24, polypeptide as defined in any one of claims 25 to 26, or antibody as defined in any one of claims to claim 29 to 30.

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